JUL 2 3 1999

K 991446

510(k) Summary

Safety and effectiveness information concerning the Biosaca from Biosys AB is summarized below.

Date Prepared April 22, 1999

Applicant

BIOSYS AB (publ)
Vasaplatsen 8
SE-411 34 Göteborg
Telephone: +46 31 774 21 25
Fax: +46 31 13 98 54
e-mail: info@biosys.se

Contact Anne Mari Nedevska, Technical Administration Manager

Device Name BIOSACA

Common Name Biological Signal Recorder

Classification The BIOSACA has been placed into class II (Reference K984580).

Product Code	Name	21 CFR
GWQ	Electroencephalograph	882.1400

Submission Correspondent

Jane B. Campbell
J. & D. Campbell Associates, Inc.
485 LaRoe Road
Chester, New York 10918
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e-mail: jdca@warwick.net

Predicate Devices B I O S A C A , Biosys AB (K984580)

Embla, Flaga hf. (K971813)

Device Description The BIOSACA is a multi-functional and an ambulatory recording device. It is an ambulatory system for the recording, monitoring, storage and transfer of up to 22 bioparameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, body movements etc. There are applications for the BIOSACA in neurological, cardiology and sleep disorder diagnoses.

Function

The BIOSACA is a biological signal recorder able to receive and record up to 22 bioparameters - 16 from two headboxes, AC and/or DC, three from the pulse oximeter and three from the sensor pad.

Intended Use

The B I O S A C A equipment is indicated for use in the recording, displaying, monitoring, printing and storage of human bioparameters such as brain, heart and muscle activity, eye movement, breathing and body movements.

The B I O S A C A is designed for stationary, ambulatory and mobile operation and may be used in either the patient's home, the hospital or other environments, enabling patients to be investigated under as realistic conditions as possible.

The B I O S A C A unit is intended for use on an adult population. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1999

Biosys AB
c/o Ms. Jane B. Campbell
J. & D. Campbell Associates, Inc.
485 LaRoe Road
Chester, New York 10918

Re: K991446
Trade Name: Biosaca System, Model 800
Regulatory Class: II
Product Code: GWQ, GWL, and MNR
Dated: April 22, 1999
Received: April 26, 1999

Dear Ms. Campbell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 991446

Device Name: BIOSACA

Indications for Use:

The BIOSACA equipment is indicated for use in the recording, displaying, monitoring, printing and storage of human bioparameters such as brain, heart and muscle activity, eye movement, breathing and body movements.

The BIOSACA is designed for stationary, ambulatory and mobile operation and may be used in either the patient's home, the hospital or other environments, enabling patients to be investigated under as realistic conditions as possible.

The BIOSACA unit is intended for use on an adult population. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991446

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)